DRIVING IMPLICATIONS OF PRESCRIPTION MEDICATIONS

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1 A BRIEF STATEMENT OF THE ISSUE

Medications have different and variable effects on driving performance. Furthermore, apart from the nature of the medications, there are other factors that interact to determine the possible influence of medications and associated side-effects on driving. This paper examines the extent to which prescribed medications and associated factors represent a road safety concern.

2 AN ASSESSMENT OF THE ROAD SAFETY ISSUE

There are approximately 600 different drug substances listed on the schedule of medications supported by the Pharmaceutical Benefits Scheme (PBS), not including the various dosage types and strengths. The pharmaceutical industry in Australia comprises around 120 companies with an annual turnover of approximately $6 billion and has been growing at a rapid pace over the past decade. Between 1991 and 2001, the number of drugs prescribed under the PBS increased by fifty per cent (Productivity Commission 2001) and expenditure on subsidised pharmaceuticals in Australia grew at 10.5% per annum between 1994/95 and 2004/05 (Australian Institute of Health and Welfare 2006).

Around 20-25% of prescription drugs affect the central nervous system, either by depressing or stimulating its function (Vingilis & MacDonald 2000; Austrian Road Safety Board 2003). As the central nervous system is the control network for the entire body and responsible for psychomotor performance (perception, reaction, cognition), these drugs have the potential to impact upon a driver's response to hazards, coordination or concentration, thereby changing the likelihood of having a crash.

Therapeutic or secondary effects of medications include: somnolence; loss of psychomotor co-ordination; behavioural changes which can lead to risk-taking and altered estimation of speed and distance; balance disturbance (for example vertigo); and sensory disturbances. Furthermore, there are many factors that interact to determine the possible influence of medications and associated side-effects on driving. These could include: medication dosage; interaction with alcohol; time after ingestion; the development of tolerance to the medication; polypharmacy; the individual's age; underlying pathologies; uses; and the taker's general physical and psychological condition.

3 CURRENT PRACTICES AND POLICIES IN AUSTRALASIAN JURISDICTIONS

For both Australia and New Zealand, the Austroads 'Assessing Fitness to Drive' management guidelines are a basic source of information in relation to prescription drug use and driving. The guidelines list the major drug groups, together with advice about each group's general impact upon driving ability, and are explicit in warning health professionals about possible risks:

> In all cases when health professionals are prescribing or dispensing medications (including across-the-counter and 'alternative' medications), they should consider any possible effects on driving skills and inform the patient. Failure to do so may have medico-legal consequences for the practitioner in the event of a crash involving the patient, particularly in the case of commercial vehicle drivers (Austroads 2003, page 53).

Drivers are also obliged to report adverse medical conditions and their related treatments, including prescribed medications, to their relevant licensing authority. The licensing authority will then review its decision to licence that person in consultation with the individual's doctor.

The International Council on Alcohol, Drugs & Traffic Safety (ICADTS) has also produced a list of medicinal drugs categorised according to their impairing properties (ICADTS, 2006). These guidelines are intended for prescribing doctors and pharmacists to enable them to identify the safest alternatives from the therapeutic class in which they are prescribing.

4 A REVIEW OF THE RESEARCH

4.1 Drugs and driving performance

Due to each person's individual level of drug sensitivity, variable side effects, and differing degrees of underlying pathologies, the detection of a drug alone does not equate to poor driving performance. For some drugs, the 'half-life' of a drug (the amount of time required for a drug to fall to half its original concentration) will also play a role in how and for how long a given drug impacts upon a driver's performance. Furthermore, not all prescription drugs should be regarded as being harmful to driving.

Therefore, previous research investigating the role of specific drugs in crashes is important for understanding their impact on road safety. This section outlines research studies examining the relationship between specific drugs and driving performance or crash risk. A broad qualification needs to be made to the following findings: any identification of an association between a given drug and risk factors cannot be taken to mean that use of that drug should cease. It might well be, for example, that an individual with a given condition would have a higher crash risk if that condition were left untreated.

4.1.1 Benzodiazepines

(Diazepam/ Valium, Ducene; Flunitrazepam/Rohypnol; Temazepam/ Normison, Euhypnos; Oxazepam/Serepax)

Benzodiazepines are psychomotor depressants, which are prescribed to help relieve acute symptoms of stress, anxiety and insomnia (Australian Drug Foundation undated). Usually they are prescribed for short-term use, due to their potential for abuse (O'Brien 2005). Benzodiazepines have one of two types of actions: sedative/hypnotic, which will induce sleep, or anxiolytic, which will reduce anxiety. In 1992-93, benzodiazepines, sedatives and hypnotics, accounted for 6% of PBS prescriptions (South Australian Government 2000).

- Using a linked database, Neutel et al (1995) examined the medical insurance, prescription drug and hospital in-patient records from 323,658 Canadians – some of whom filled prescriptions for hypnotic (n= 78,000) or anxiolytic (n=148,000) benzodiazepines during the study period with the rest acting as controls (n= 98,000). The odds of being involved in a crash were 6.5 (95% CI: 1.9 – 22.4) for hypnotic benzodiazepines and 5.6 (95%CI: 1.7- 18.4) for anxiolytic benzodiazepine within the first two weeks of commencing the course of drugs. The authors noted, however, that prescription records provide only limited exposure data on actual benzodiazepine use, as it is unknown whether the drug was actually taken and in what quantities. It is also worth noting that the patients' records reviewed in this study included anyone admitted to hospital after a motor vehicle crash and not drivers specifically.
- Hemmelgarn et al reviewed driver licence files, police reports of injurious crashes, and health insurance records from 224,734 drivers aged 67 to 84 years (using a nested case-control design of 5579 cases and 55790 controls). This study found that drivers taking benzodiazepines had an adjusted rate ratio[1] of 1.45 (95 CI%: 1.04-2.03) in the first week of using drugs with longer half-lives and a rate ratio of 1.26 (95% CI: 1.09-1.45) for those who had been taking drugs with longer half-lives continuously for up to 1 year. However, there were no significant findings for the benzodiazepines that have shorter half-lives.
- In another study in the United States, 901 older drivers were selected from the Alabama Department of Public Safety driving records: 244 were at-fault drivers involved in crashes; 182 were not at-fault drivers involved in crashes; and 475 drivers were not involved in crashes. Information about medical conditions and medications was sought via a telephone interview. The authors found a heightened at-fault crash risk associated with benzodiazepine use. However the association was not statistically significant (OR: 5.2 95% CI: 0.9 - 30.0), (McGwin et al 2000).
- Three additional case-control studies have found significantly heightened risks for benzodiazepine use among injured drivers in France (OR: 1.7, 95% CI: 1.2–2.4) (Mura et al 2003), patients at a trauma unit in the Netherlands (adjusted OR 5.1, 95% CI: 1.8–14.0) (Movig et al 2004), and a case-crossover design study of crash-involved drivers in the United Kingdom using benzodiazepines with a long plasma half-life (n=101, OR: 2·03, 95% CI: 1·41–2·93) (Barbone et al 1998).

[1] An adjusted rate ratio is a statistical procedure that is done to ensure that valid comparisons can be made between groups without differences in their composition affecting the results. In this case, rate ratios were adjusted for age, sex, residence, chronic disease score, other central nervous system drug exposure $\leq$60 days prior to the crash, previous motor vehicle crashes and exposure to other benzodiazepines $\leq$ 60 days prior to the crash.

- Using culpability analysis to determine whether crash-involved drivers were at-fault, Drummer et al (2004) and Longo et al (2001) both found benzodiazepines to have a heightened risk of culpability, OR: 1.27 (95% CI: 0.5–3.3) and OR: 2.0 (significant at therapeutic or above-therapeutic doses), respectively. Drummer et al noted that the power for detecting the culpability of drivers who had taken benzodiazepines was reduced due to the fact that alcohol or other drugs were often involved as well.

4.1.2 Tricyclic anti-depressants

(Tryptanol/amitryptiline; Sinequan/doxepin; Prothiade/dothiepin)

Tricyclic anti-depressants are an older class of anti-depressant drugs. Although they are still indicated for a variety of conditions, they have been used less commonly since the development of newer classes of antidepressant drugs because of their potential for side effects, such as drowsiness or cognitive difficulties.

- Evidence was presented at the Inquiry into the Effects of Drugs (Other than Alcohol) on Road Safety in Victoria held by the Victorian Parliament that tricyclic anti-depressants alone or combined with alcohol can produce impairment equivalent to illegal doses of alcohol (0.08 percent BAC in the United Kingdom). It was also contended that people receiving tricyclic antidepressants have stopping distances greater than drivers with a blood alcohol content of 0.08 when travelling at a speed of 70 kph (Road Safety Committee 1996).
- In a laboratory-based study of 24 healthy adult and elderly volunteer participants with some receiving just one dose of one tricyclic antidepressant (imipramine), the authors found a negative impact on lateral position (increased weaving out of lane) in the adult group during a driving test using a specially instrumented car, although this effect diminished after repeated doses (van Laar et al 1995), which could be due to tolerance to the drug.
- Another laboratory based study of 16 males aged 21 to 28 looked at the effects of a newer antidepressant, a selective serotonin re-uptake inhibitor (paroxetine), and a tricyclic antidepressant (amitryptiline) on driving performance during a driving test in highway traffic using a specially instrumented car. The group receiving tricyclic antidepressants were found to have significantly worse lateral deviation control, and 22% of the driving tests for these subjects had to be discontinued due to safety concerns related to the participants' drowsiness. However, the authors noted that nearly all of the adverse effects tended to dissipate with repeated dosing and were nearly gone after a week (Robbe & O'Hanlon 1995), which could be due to tolerance to the drug.
- Two additional laboratory-based studies of healthy volunteers found no effect on driving performance for two types of tricyclic anti-depressants, but effects were noted in most performance measures for the other drug (Mianserin) which is a tetracyclic antidepressant and has sedative properties that are known to cause drowsiness and fatigue (Ramaekers et al 1994; Ramaekers et al 1995). The effects of the Mianserin did not diminish during the course of the treatment period, which lasted for eight days.

All of these studies should be interpreted in light of the fact that healthy volunteers were used as subjects and, in some cases, lower than normally prescribed doses were given. However, several epidemiological studies have also been conducted which looked at the association between cyclic anti-depressant use and crash risk.

- Ray et al (1992) reviewed the health insurance records, driver's licence files and police reports of injurious crashes among a cohort of 16,262 people aged 65-84 with current driver's licences. Measures were taken to exclude people from the study who were unlikely to be current drivers, despite their having a valid driver's licence. They found users of cyclic antidepressants had a relative risk of 2.2 (95% CI 1.3-3.5) and this risk increased with higher doses (doses of 125 mg or greater of amitriptyline), RR: 5.5, 95% CI 2.6-11.6.
- Leveille et al (1994) conducted a case-control study of older drivers (over age 65 years) enrolled in a health maintenance organisation (pre-paid health plan), including 234 cases (people seeking treatment for motor vehicle collision injuries) and 447 controls (matched on age, gender, county and not seeking treatment for collision-related injuries). They found current users of cyclic antidepressants had an adjusted relative risk of 2.3 (95% CI= 1.1-4.8) for injurious collisions.

4.1.3 Narcotic analgesics / Opiates

(Morphine/Mophalgin.; Codeine/Panadeine, Codral Forte; Methadone/Physeptone; Pethidine; Propoxyphene/Doloxene, Digesic, Capadex; Buprenorphine)

Opiate analgesics are generally used for pain relief and are commonly prescribed to patients receiving palliative care, with non-malignant chronic pain or with withdrawal symptoms from illegal opiates such as heroin. Some of their side effects may include impaired reaction time, impaired vision, confusion, dizziness or delirium. Over time, patients receiving opiate analgesics can develop a tolerance to them, requiring increased doses for pain relief. Opiate medications are also known to be addictive and some types of opiates may be abused by individuals when they are unable to obtain illegal drugs.

- A case-control study (25 cancer patients not receiving drugs and 24 of whom were receiving morphine) found a difference between the two groups' performance on two psychomotor tasks: Q1 (assessing attention capacity) and LL5 (assessing concentration and structuring ability). However, the authors noted that it was unclear how these differences would affect driving performance, if at all (Vainio 1995).
- In two other laboratory-based studies, one using a computerised test battery of driving ability (Gaertner et al 2006) and the other using a validated driving test battery (Sabatowski et al 2003) no differences were found between cancer patients receiving long-term opioids (oxycodone and fetanyl, respectively) for chronic pain and healthy controls.
- In the studies of older drivers described previously, Leveille et al (1994) found current opioid analgesic use was associated with an adjusted relative risk of 1.8 (95% CI = 1.0-3.4) and Ray et al (1992) did not find an increased crash risk associated with oral opioid analgesic prescriptions.

4.1.4 Other Drugs

- A review of 130 publications relating to the side effects of antihistamines, identified 31 studies relating to driving and piloting skills. There were differences noted between the first generation antihistamines, which are older and tend to act less selectively, and the newer second-generation antihistamines, which tend to have fewer side effects. The findings for first generation antihistamines showed that 89% (8 of 9) studies showed significant impairment in on-road driving performance, while only 10% (2 of 20) of those relating to second generation showed significant impairments. The epidemiological evidence studying the association between first generation antihistamine use and motor vehicle crashes is slight, but ambiguous (Moskowitz and Wilkinson 2004). However, Leveille et al (1994) and Ray et al (1992) found no association of antihistamines with crash risk.

- The role of over-the-counter and prescription stimulants (Ephedrine, Pseudoephedrine; Sudafed; Phentermine/Duromine) have also been questioned in relation to driving ability. Drummer (2004) found the culpability ratio of truck drivers with stimulants detected in their samples to be heightened but only marginally significant (OR: 8.83, 95% CI 1.00–78). Among all drivers, the ratio was heightened but not significant (OR: 2.27, 95% CI 0.9–5.6). This analysis included licit and illicit stimulants.[2] Movig et al (2004) in a case-control study of injured drivers found amphetamines to have a heightened but not significant association with culpability (adjusted OR: 2.10, 95% CI 0.66–6.73) in a case-control study of injured drivers, but these findings also included licit and illicit substances.

- Using a nested case-control approach from a cohort of Canadian drivers, Etminan et al (2004) found subjects who had been involved in an injurious motor vehicle crash were more likely to have a dispensed prescription for lithium within the past year than among control subjects (rate ratio 2.08, 95% CI: 1.11 to 3.90).

4.2 Descriptive studies of medicinal drugs in crash-involved drivers

Research overseas and in Australia has sought to identify the incidence of certain classes of prescription drugs in the blood or saliva samples of drivers suspected of being under the influence as well as crash-involved drivers. However, the scope of the hazard posed by prescription drug use and driving is hard to identify. A major limitation of these studies is that ethical and practical limitations only enable samples to be taken from drivers who are fatally or seriously injured, who represent a small proportion of all crash-involved drivers. Post-mortem changes in fatally injured drivers and iatrogenic drug treatments can also impact toxicological findings.

4.2.1 Overseas studies

Table 1 presents a summary of overseas studies, looking at the incidence of various prescription drugs in the driving population.

[2] amphetamine, methamphetamine, methylenedioxymethamphetamine, ephedrine, pseudoephedrine, phentermine and cocaine.

Table 1: International Studies of the incidence of drug use and driving (illicit and medicinal drugs identified)

Sample	Drug detected	Detection rate	Notes
Fatalities			
5745 blood or urine samples from drivers in fatal road crashes between 1991 and 2000 (Carmen del Rio 2002)	Alcohol (n=2517) Illicit drugs (n=504) Benzodiazepines (n=196) Anti-depressant drugs (n=33) Analgesics (n=26) Anti-epileptic drugs (n=18) Other (n= 49)	43.8% 8.8% 3.4% 0.6% 0.4% 0.3% 0.9%	The authors note that in 65.8% of cases, the medicinal drugs were taken either in combination with other drugs and/or alcohol
Blood and/or urine samples from 197 deceased drivers were investigated between 1996 and 2000 in Hong Kong. (Cheng et al 2005)	Alcohol (n=73) CNS stimulants (including designer drugs like ecstasy) (n=5) Cannabis (n=4) Benzodiazepines (n=2) Ketamine (n=1)	37% 2.5% 2.0% 1.0% 0.5%	
Blood samples taken from 159 driver fatalities (57% of all fatally injured drivers in this period in Norway) (Gjerde et al 1993)	Alcohol (BAC ≥ .05) (n=42) Benzodiazepines (n=24) Narcotic analgesics (n=3)	27.0% 15.1% 1.9%	The benzodiazepines were used in combination with other drugs or alcohol in approximately half of cases.
Non-fatal crashes			
333 injured drivers in Denmark who were treated in hospital were asked to provide a saliva sample, a blood sample or both. Blood samples were only obtainable from 45 participants. (Klemenjak et al 2005)	Blood screening showed: MDMA and MDA (n=7) Cannabis (n=7) Benzodiazepines (n=5) Opiates (n=2) Amphetamine, methamphetamine, Cocaine and its metabolites (n=4)	 15.6% 15.6% 11.1% 4.4% 8.9%	
115 crash-responsible injured drivers consecutively presenting to the emergency department in an Italian hospital were asked to provide urine samples. (Giovanardi et al 2005)	Marijuana (n=22) Alcohol (n=12) Benzodiazepines (n=11) Amphetamines (n=8) Cocaine (n=7)	19% 10% 10% 7% 6%	The majority of drivers positive for benzodiazepines were 41–70 years old, while most drivers positive for alcohol or other drugs were 21–40 years old.

Sample	Drug detected	Detection rate	Notes
Urine analyses were performed on 414 injured drivers who presented to an emergency department in Colorado, USA within 1 hour of their crash. (Lowenstein & Koziol-McLain 2001)	Marijuana (n= 70) Alcohol (n=57) Cocaine metabolites (n=15) Narcotic analgesics (n= 13) Benzodiazepines (n=5) Amphetamines (n=3)	17% 14% 3.6% 3.1% 1.2% 0.7%	
Blood and urine samples from 322 motor vehicle crash victims admitted for treatment related to a MVC in a trauma unit in Maryland, USA. (Walsh et al 2004)	Alcohol (n=83) Benzodiazepines (n=56) THC cannabinoids (n=53) Cocaine (n=36) Opiates (n=29) Barbiturates (n=26) Methamphetamine (n=10) Amphetamine (n=4)	25.8% 17.4% 16.5% 11.2% 9.0% 8.1% 3.1% 1.2%	61% of the patients testing positive for benzodiazepines also tested positive for an illegal drug, most frequently marijuana
Drivers suspected of being under the influence/ randomly stopped			
Blood specimens were analyzed from 210 drivers apprehended and requested by authorities for alcohol testing in Luxembourg from autumn 2001 to spring 2002 (Appenzeller 2005)	Alcohol only (n= 130) Alcohol & medicinal drug (n=36) No substance (n=16) Alcohol & illicit drug only (n=15) Medicinal drug (n=6) Alcohol, medicinal & illicit drug (n=4) Illicit drug & medicinal drug (n=2) Illicit drug only (n= 1)	61.9% 17.1% 7.6% 7.1% 2.9% 1.9% 1.0% 0.5%	Poly-drug use was observed in 27.6% of drivers (90.6% of drug consumers).
440 drivers suspected of driving under the influence of drug (DUID) were collected and examined during a 2 year period ranging from 2002 to 2003 in Switzerland. (Augsburger 2005)	Cannabinoids (n=261) Alcohol/ Ethanol (n= 203) Benzodiazepines (n =57) Cocaine & metabolites (n=55) Amphetamines (n =39) Opiates (n=39) Methadone (n=31)	59% 46% 13% 13% 9% 9% 7%	
Saliva samples from 896 randomly stopped Danish drivers. (Behrensdorff & Steentoft 2003)	Opiates (n=24) Cannabis (n=21) Amphetamine/ methamphetamine (n=14) Benzodiazepines (incl. hypnotics and tranquilizers) (n=8) Cocaine (n=2)	2.7% 2.3% 1.6% 0.9% 0.2%	The authors noted that many of the commonly prescribed benzodiazepines in Denmark were not detectable with the screening equipment used in the study, thereby leading to a likely under-estimation of the true prevalence.
212 blood samples collected from traffic users in Poland suspected of driving under the influence (Chowaniec at al 2005)	Opiates (n=18) Amphetamine (n=17) Benzodiazepines (n=13) Barbiturates (n=10)	8.5% 8.0% 6.1% 4.7%	

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333 injured drivers in Denmark who were treated in hospital were asked to provide a saliva sample, a blood sample or both. Blood samples were only obtainable from 45 participants. (Klemenjak et al 2005)	Blood screening showed: MDMA and MDA (n=7) Cannabis (n=7) Benzodiazepines (n=5) Opiates (n=2) Amphetamine, methamphetamine, Cocaine and its metabolites (n=4)	 15.6% 15.6% 11.1% 4.4% 8.9%	
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4.2.2 Australian research

Drummer et al (2003), using a sample of 3398 driver fatalities from Victoria, New South Wales and Western Australia, found :

- 4.9% (n=167) of blood samples contained opioids (methadone, morphine or codeine)
- 4.1% (n=138) contained benzodiazepines (diazepam, oxazepam and temazepam)
- 1.8% (n=61) contained the stimulants pseudoephedrine or ephedrine
- 1.5% (n = 51) contained methamphetamine
- 0.4% (n=12) contained phentermine.

Longo et al (2000) in South Australia investigated the blood samples of 2500 non-fatal, crash-involved drivers and found:

- 1.8% (n=46) contained benzodiazepines alone
- 1.6% (n= 40) contained benzodiazepines with other drugs or alcohol
- 0.6% (n=15) of drivers tested positive for a stimulant available by prescription in Australia, although 50% of the drugs were detected above therapeutic levels suggesting that these drivers were not using the drugs in accordance with a doctor's instructions.

5 POLITICAL, SOCIAL AND OTHER FACTORS

Despite the research evidence indicating a heightened risk associated with the use of specific drugs, taking a medication alone is not a predictor of poor driving performance, especially when the medication is taken under the supervision of a medical practitioner (Dobbs 2001). Factors such as the underlying medical condition, tolerance to the drug and concomitant medications will all play a role in an individual's general cognitive state and driving performance under the influence of prescription drugs. However, the greatest concern in regards to medication use and driving may be that drugs are not always taken as directed, either unintentionally (misuse) or intentionally (controlled substance abuse).

5.1 Misuse

One study in a primary care clinic in the United States interviewed 395 English-speaking patients about their understanding of prescription medication label instructions. Almost half (46.3%) of these patients misunderstood one or more of the prescription label instructions, and the prevalence increased among patients with low literacy levels (62.7%) (Davis et al 2006).

Another study of 100 older adults in the United States, found that 53% did not adhere to the directions for taking their prescription medications due to issues with the cost, their memory or the number of medications (Roth and Ivey 2005).

5.2 Controlled substance abuse

Evidence from the United States also suggests that prescription and over-the-counter medication abuse may be on the rise among teenagers. According to the 2006 US National Institute on Drug Abuse (NDIA) survey of 8th, 10th and 12th graders, some commonly abused drugs types among adolescents are opiate analgesics (hydrocodone, oxycodone) and stimulants (ritalin, adderall) (Kuehn 2007). It was also noted that the drugs are often taken in combination.

A literature review on drug abuse among older adults suggested that as many as 16% of older Americans (aged 65 and older) may abuse prescription drugs (Simoni-Wastila et al 2006).

Likewise, in Australia, the 1998 National Household Survey (South Australian Government 2000) collected data regarding the rates in South Australia of 'ever used' and 'used within the last 12 months' of prescription and over the-counter drugs for non-medical purposes.

The survey revealed the following:

- approximately 14% of South Australians had ever misused analgesics
- approximately 6% had misused analgesics within the last 12 months

- approximately 6% had ever misused tranquillisers
- approximately 3.5% had misused tranquillisers within the last 12 months.

As many prescription drugs prone to abuse can be easily obtained on the internet without prescriptions (St George et al 2004; Schifano et al 2006), the means to acquire and abuse controlled substances is now far more accessible than it was in the past.

6 CONCLUSIONS

The research suggests that driving under the influence of drugs is prevalent in Australia and that some of these drugs may be more impairing than others. The differences in risk for various medications should be brought to the attention of prescribing doctors, so that they may choose the least impairing medications for their patients. Further research is required on the implications of various medications for driving and clear guidelines should be made available to clinicians on the impairing effects of the drugs.

Additionally, clear information needs to be provided to patients regarding the appropriate uses and dosages of their medicines. Education and screening programs for controlled substance abuse may also be considered as preventative measures. Further research is required to gain a better estimate of the prevalence for prescription drug involvement in crashes.

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